## UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

UNIVERSITY OF NEW MEXICO (5,747,332, 6,066,716, and 6,433,141).

Junior Party,

V.

**FORDHAM UNIVERSITY** (09/090,754),

Senior Party.

Interference No. 104,761

Before SCHAFER, TORCZON, and SPIEGEL, <u>Administrative Patent Judges</u>.

TORCZON, <u>Administrative Patent Judge</u>.

# and JUDGMENT (PURSUANT TO 37 CFR § 1.658)

### INTRODUCTION

Following a decision on motions (Paper 98), the University of New Mexico [UNM] was placed under an order to show cause (Paper 99) why judgment should not be entered against UNM. The order to show cause noted that UNM, as junior party, failed to overcome Fordham's effective filing date. In the decision on motions, UNM's attack on Fordham's effective filing date also failed. The order to show cause also noted a pending Fordham motion to add another UNM patent to the interference.

In response, both parties have requested reconsideration of the decision on motions, UNM has responded to the order to show cause, and UNM has opposed

Fordham's motion to add another UNM patent. UNM is seeking reconsideration (Paper 100) of the decision to deny its Preliminary Motion 2, in which UNM argued that Fordham's claims would have been obvious to a person having ordinary skill in the art at the time of Fordham's invention. Fordham seeks reconsideration (Paper 102) of the decision to deny the part of its Preliminary Motion 4, in which Fordham argued that UNM's 716 claims 7-12 should correspond to count 3.

#### **FINDINGS and CONCLUSIONS**

Enumerated findings are supported by at least a preponderance of the evidence. The ultimate burden of proof for a motion lies with the movant. 37 C.F.R. § 1.637(a). The ultimate burden on priority lies with the junior party. 37 C.F.R. § 1.657(a). The burden on reconsideration lies with the requester. 37 C.F.R. §§ 1.640(c) and 1.658(b).

#### Reconsideration of UNM Preliminary Motion 2

- [1] UNM moved to have Fordham University's claims held unpatentable under 35 U.S.C. 103.
- [2] The motion cites the following references as the basis for unpatentability:

Palleros et al., "Hsp-70 Protein Complexes", 289 J. Biol. Chem. 13107 (1994) [2030]<sup>1</sup>

Liberek et al.,"Escherichia coli DnaJ and GrpE heat shock proteins jointly stimulate ATPase activity of DnaK", 88 Proc. Nat'l Acad. Sci. 2874 (1991) [2031]

Liberek et al., "Escherichia coli DnaK Chaperone, the 70 kDa Heat Shock Protein Eukaryotic Equivalent, Changes Conformation upon ATP Hydrolysis, Thus Triggering Its Dissociation from a Bound Target Protein", 266 J. Biol. Chem. 14491 (1991) [2032]

<sup>1</sup> UNM exhibits are numbered from 2001; Fordham's, from 1001.

Welch et al., "Rapid Purification of Mammalian 70,000-Dalton Stress Proteins: Affinity of the Proteins for Nucleotides", 5 Mol. & Cell. Biol. 1229 (1985) [2033]

Lewis et al., "Involvement of ATP in the nuclear and nucleolar functions of the 70 kd heat shock protein", 4 EMBO J. 3137 (1985) [2035]

Bochner et al., "Escherichia coli DnaK protein possesses a 5'-nucleotidase activity that is inhibited by AppppA", 168 J. Bacteriol. 931 (1986) [2036]

Kassenbrock et al., "Interaction of heavy chain binding protein (BiP/GRP78) with adenine nucleotides" 8 EMBO J. 1461 (1989) [2037]

Skowyra et al., "The E. coli dnaK gene product, the hsp70 homolog, can reactivate heat-inactivated RNA polymerase in an ATP hydrolysis-dependent manner", 62 Cell 939 (1990) [2038]

Sadis et al., "Biochemical and biophysical comparison of bacterial DnaK and mammalian hsc73, two members of an ancient stress protein family", Curr. Res. in Prot. Chem. 339 (1990) [2039]

Flaherty et al., "Three-dimensional structure of the ATPase fragment of a 70K heat-shock cognate protein", 346 Nature 623 (1990) [2040]

Sherman et al., "Formation in vitro of complexes between an abnormal fusion protein and heat shock proteins from Escherichia coli and yeast mitochondria", 173 J. Bacteriol. 7249 (1991) [2041]

Sadis et al., "Unfolded proteins stimulate molecular chaperone hsc70 ATPase by accelerating ADP/ATP exchange" 31 Biochem. 9406 (1992) [2042]

Richarme et al., "Specificity of the Escherichia coli chaperon DnaK (70-kDa heat shock protein) for hydrophobic amino acids", 268 J. Biol. Chem. 24074 (1993) [2043]

Blond-Elguindi et al., "Peptide-dependent stimulation of the ATPase activity of the molecular chaperone BiP is the result of conversion of oligomers to active monomers", 268 J. Biol. Chem. 12730 (1993) [2044]

- [3] UNM also relied on the Welch declaration [2028], which cited the same papers.
- [4] The decision on motions concluded:

The prior art UNM cited suggests that an ADP substrate could be substituted for the ATP substrate in the method of Welch 1985 if one seeks to isolate hsp-protein complexes. The motivation for the modification, however, hinges on the desirability of making hsp-protein complexes. "The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification." In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Without a motivation to make such complexes, the fact that it could be done is academic. What motivation there is appears to come from the work of one of Fordham's inventors and was not cited by UNM against Fordham.

Moreover, it is not clear why a person having ordinary skill in the art would [have] expect[ed] the substitution to work. After all, Welch 1985 emphasized that its method isolated heat-shock proteins in their native form. Palleros, using a different method, found that adding ADP to (or substituting it for ATP in) the mobile phase of the chromatography system had the effect of stabilizing the complex much more than ATP alone. Assuming that a person having ordinary skill in the art had motivation to isolate hsp-protein complexes, the combined teachings of Welch 1985 and Palleros provide an experiment to try rather than a reasonable expectation of success. See In re Dow Chemical Co., 837 F.2d, 469, 473, 5 USPQ2d 1529, 1532 (Fed. Cir. 1985) (rejecting an "obvious to experiment" approach).

- [5] In requesting reconsideration of the decision, UNM cites two Fordham exhibits (Paper 100 at 11, citing Fordham exhibit 1019², and at 12, citing 1018³) and the characterization of the prior art in UNM's 332 patent [2066].
- [6] UNM stated its characterization of the prior art in its 332 patent as a material fact (UNM Prel. Mot. 2 at 4, Fact 2).
- [7] Fordham denied that characterization (Fordham Opp. 2 at 3).

<sup>&</sup>lt;sup>2</sup> H. Udono & P.K. Srivastava, "Heat Shock Protein 70-associated Peptides Elicit Specific Cancer Immunity", 178 J. Exp. Med. 1391 (1993).

<sup>&</sup>lt;sup>3</sup> N.E. Blachere et al., "Heat Shock Protein Vaccines Against Cancer", 14 J. Immuno I. 352 (1993). Fordham's named inventor, Pramod K. Srivastava, is a co-author.

The UNM 332 patent is not prior art against Fordham's claims (except as a basis for a priority contest under 35 U.S.C. 102(g)(1)/135(a)). Moreover, while UNM's characterization of the prior art might be available as an admission against UNM, it is hardly evidence of unpatentability against Fordham.<sup>4</sup>

- [8] Neither of the Fordham exhibits now cited appear to have been cited in UNM's preliminary motion 2.
- [9] Both exhibits are 1993 journal articles that list the sole inventor named on Fordham's involved application, P.K. Srivastava, as a co-author.
- [10] UNM has not alleged that the papers in the Fordham exhibits were not available to UNM at the time it filed its motion.

It is axiomatic that the panel cannot have misapprehended or failed to appreciate an argument that was never made. Accord Rumsfeld v. Freedom NY, Inc., No. 02-1105, -1130, 2003 WL 22339495, at \*1 (Fed. Cir. 2003) (Argument not raised in opening brief is waived for purposes of rehearing). Moreover, Fordham was not on notice of the basis now advanced for the unpatentability of its claims. Consequently, we do not have the benefit of Fordham's explanation of why its claims would be patentable despite these additional references. The alleged error in the decision on motions is our failure to enter what, in effect, would have been a new ground of rejection.

<sup>&</sup>lt;sup>4</sup> The Decision on Motions noted the apparent admission, but declined to hold UNM's claims unpatentable because the issue had not been developed in the motions process (Paper 98 at 47).

An administrative patent judge may exercise discretion to explore a new ground of rejection. 37 C.F.R. § 1.641. Moreover, the Board may exercise its discretion to recommend that an examiner explore the potential rejection, 37 C.F.R. § 1.659. Finally, we may simply decline to take any action at all.

We decline to proceed under § 1.641 at this late date on what might well prove to be a blind alley. Since Fordham is an applicant whose application will ultimately be remanded to an examiner, any remaining questions of unpatentability can be addressed in that forum.<sup>5</sup> Cf. In re Hounsfield, 699 F.2d 1320, 1324, 216 USPQ 1045, 1048 (Fed. Cir. 1983) (refusing to entertain a late rejection but noting that the agency could explore it on remand). UNM has had its opportunity to make out a case for unpatentability.

The decision to deny UNM Preliminary Motion 2 has been reconsidered, but relief from that decision is DENIED.

#### Reconsideration of Fordham Preliminary Motion 4

- [11] Fordham moved to have several additional UNM claims designated as corresponding to the counts, including having UNM 716 claims 7-12 designated as corresponding to count 3.
- [12] The Board held (Paper 98 at 45):

As noted in the fact-finding, we do not consider the hsp110 family proteins of UNM 716 claim 7 to be anticipated by the hsp70 family proteins enumerated in UNM claims 13, 19, and 25. Moreover, claims 7-

<sup>&</sup>lt;sup>5</sup> We note that both of the Srivastava co-authored articles in question are listed as references on the front cover of the Forham patent that issued from the parent application of Fordham's involved application. UNM has not suggested that the articles were not previously available to it.

12 are composition claims and are not stated in terms of a product-by-process. Consequently, Fordham's obviousness analysis must proceed from the obviousness of hsp110 family members from the enumerated hsp70 family members.

While the parties dispute whether the hsp110 family is part of the hsp70 family based on the degree of sequence and domain identity or similarity between hsp110 and DnaK, we are provided very little motivation for the substitution of an enumerated (in claims 13, 19, and 25) hsp70 family member with an hsp110 subfamily member, or with the modification of such an hsp70 family member into an hsp110 family member. In the context of UNM's disclosure, the only thing linking these heat-shock proteins is the fact that they (and members of other hsp families) may be purified in the same way. Since claim 7 is not a product-by-process claim, however, this process similarity does not help make out a case for obviousness. We cannot conclude that hsp110 complexes would have been obvious in view of other hsp70 complexes. If anything, the evidence suggests that a person having ordinary skill in the art would have expected hsp110 complexes to have been very different.

[13] Fordham contends that the decision on motions applied the wrong standard for determining the separate patentability of the subject matter of UNM 716 claims 7-12 over the subject matter of count 3 (Paper 102 at 2-3):

In rejecting Fordham Preliminary Motion 4, the Board focused on the differences between hsp110 per se and e.g. DnaK per se (a representative hsp70 family member recited in Count 3) (Decision at page 45, first full paragraph). Instead, Fordham submits, the question of the patentable distinctness of UNM '716 claims 7-12 should have been established by determining whether the subject matter of the claims, i.e. ternary hsp110-ADP-peptide complexes, would have been obvious over the hsp70-ADP-peptide complexes recited in Count 3.

Although Fordham acknowledges that hsp110 and the hsp70 family members of Count 3 are different proteins, Fordham submits that the ternary hsp110-ADP-peptide complexes of UNM '716 claims 7-12 are obvious over e.g. the DnaK-ADP-peptide complexes of Count 3. More specifically, Fordham submits that in rendering the Decision concerning that part of Fordham Preliminary Motion 4 requesting that UNM '716 claims 7-12 be designated as corresponding to Count 3, the Board overlooked or misapprehended Fordham's argument that both hsp110 and e.g. DnaK have common functional domains providing the critical

biochemical traits, i.e. the ability to bind adenine nucleotides (ATP and ADP), and peptides or other proteins. In fact, the Board has concluded that "at the time of UNM's invention, the state of the art pointed to both protein-binding and ATP-binding for hsp110" (Decision, at page 42, first full paragraph, last sentence). Fordham submits that in rendering the Decision the Board has overlooked Fordham's arguments that, in view of e.g. DnaK-ADP-peptide ternary complexes of Count 3, it is obvious that hsp110, which is known to be able to bind ADP and a peptide separately, can also bind both simultaneously to provide the ternary complexes of UNM '716 claims 7-12 (see e.g. Fordham Preliminary Motion 4 at page 9; Fordham Reply Motion 4 at page 5, last two paragraphs extending onto page 6; and Fordham Reply Motion 4, at page 8, third full paragraph).

[14] While the first paragraph of the cited portion of the Board decision does suggest that the obviousness of hsp110 in view of hsp70 is the issue under consideration, the second paragraph clarifies that in fact the Board considered the motivation for substituting hsp110 for hsp70 in the hsp70-ADP-peptide complex of count 3.

Fordham focuses on the fact that hsp110-peptide complexes can be formed in the same way that hsp70-peptide complexes are formed. The Board decision does not question the similarity of the process for forming such hsp-peptide complexes. Rather the decision focuses on the motivation for substituting hsp110 for hsp70 in the process. "The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification." In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). The Board decision found no such motivation and based its decision to deny on that lack of motivation. Moreover, there is no per se rule that similar complexes made the same way are thereby obvious in view of each other, thus side-stepping the question of motivation. Cf. TorPharm, Inc. v. Ranbaxy Pharm., Inc., 336 F.3d 1322, 1327, 67 USPQ2d 1511, 1514 (Fed. Cir. 2003) (confirming the absence of a per se rule of

Univ. of New Mexico v. Fordham Univ.

unpatentability for products and methods of making such products). Fordham's request for reconsideration does not point to any overlooked motivation, so while the decision has been reconsidered, relief from the decision is DENIED.

#### **UNM's** opposition

- [15] The Board did not consider UNM's opposition (Paper 104) to Fordham's request in reaching its decision to deny Fordham relief.
- [16] Fordham had asked that the opposition be struck (Paper 105).

As discussed in Paper 105, an opposition to a request for reconsideration is not automatic under 37 C.F.R. § 1.640. That paper indicated that the opposition would be struck<sup>6</sup> if it proved unnecessary. Consequently, UNM's opposition shall be STRUCK from the record.

#### **JUDGMENT**

Neither party has requested a final hearing (Paper 105). Consequently, this interference is ripe for final judgment. The addition of UNM 141 claims 1-18 (Paper 106) does not change this conclusion since the count to which they correspond has not changed and thus the priority case available to UNM to defend these claims has not changed.

#### ORDER

Upon consideration of Fordham's miscellaneous motion 4 and UNM's opposition, UNM's and Fordham's requests for reconsideration of the decision on motions, and

<sup>&</sup>lt;sup>6</sup> Paper 105 actually says "returned", but returning a paper makes little sense in an interference with electronic filing.

UNM's response to the order to show cause, and upon reconsideration of our decision on motions, it is:

ORDERED that relief from the decision denying UNM Preliminary Motion 2 be DENIED;

FURTHER ORDERED that relief from the decision denying Fordham Preliminary

Motion 4 with regard to UNM 716 claims 7-12 be DENIED;

FURTHER ORDERED that the UNM opposition to Fordham's request for reconsideration be STRUCK from the record;

FURTHER ORDERED that judgment on priority as to Count 1 is awarded against UNM:

FURTHER ORDERED that UNM is not entitled to a patent containing claims 1, 3-5, and 7-12 of UNM's 5,747,332 patent, which correspond to Count 1;

FURTHER ORDERED that judgment on priority as to Count 3 is awarded against UNM;

FURTHER ORDERED that UNM is not entitled to a patent containing claims 13-30 of UNM's 6,066,716 patent or claims 1-18 of UNM's 6,433,141 patent, which correspond to Count 3;

FURTHER ORDERED that judgment on priority as to Count 4 is awarded against UNM;

FURTHER ORDERED that UNM is not entitled to a patent containing claims 13, 15-17, and 19-23 of UNM's 5,747,332 patent, which correspond to Count 4; and

FURTHER ORDERED that a copy of this decision be entered in the administrative record of UNM's 5,747,332 patent, 6,066,716 patent and 6,433,141 patent, and of Fordham's 09/090,754 application.

RICHARD E. SCHAFER Administrative Patent Judge

RICHARD TORCZON
Administrative Patent Judge

CAROL A. SPIEGEL Administrative Patent Judge BOARD OF PATENT APPEALS AND INTERFERENCES

INTERFERENCE TRIAL SECTION

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